

Remarks

Claims 15-22, 24 and 25 remain in the case. Claim 23 has been canceled.

The claims have been rejected under 35 USC 101, 112, 102 and 103. The claims have been substantially narrowed to reflect the data presented in this amendment. What is now claimed as a hair accelerating growth agent for canine and felines is a specific mixture of at least three alcohols out of four claimed alcohols. Support for the term “accelerating” appears in the specification at page 2, lines 5-6 and page 3, lines 16-18. The use of a mixture of alcohols is specifically supported in the Example in the specification appearing at page 4, line 10 through page 5, line 7. Additional data is now presented below together with the results.

Animal care: Dogs were housed individually, fed with Hill’s Canine Maintenance dry diet daily, and had free access to tap water during the study period. Daily amount of food given to each dog was based on its body weight so that dog’s body weight can be maintained during the study period. Other Hill’s procedures for animal care were also followed.

Anesthesia: Anesthesia was induced by intravenous injection of 2.5% pentothal and maintained by inhalation of Isoflurane gas. Anesthesia was administered and monitored by a trained technician under the supervision of a licensed veterinarian. Following skin treatments, each dog was returned to its respective cage and monitored until sternal recumbency was achieved.

Skin preparation: An area of about 8” x 8” on both sides of flank areas was clipped using an electronic clipper. Five treatment spots were assigned to each clipped area using a transparent plastic sheet with five punched holes that indicate treatment spots. The sheet was used as a guide so that same spot of skin can be treated repeatedly at different times.

Skin treatments: A total of nine different skin treatments were conducted on each dog. Each treatment was repeated six times with 2 weeks of interval. They were as follows:

1. Thirty-six times of treatment with D-Squame sampling discs (CuDerm Corp., Dallas, TX).
2. Treatment 1 and extraction with deionized water.
3. Treatment 1 and extraction with 5% methanol in water.
4. Treatment 1 and extraction with 5% isopropyl alcohol in water.
5. Treatment 1 and extraction with 90% ethanol in water.
6. Treatment 1 and extraction with a mixture of 90% ethanol and 5% methanol in water.
7. Treatment 1 and extraction with a mixture of 90% ethanol and 5% isopropyl alcohol in water.
8. Extraction with a mixture of 90% ethanol, 5% methanol, and 5% isopropyl alcohol in water.
9. Treatment 1 and treatment 8.

Treatment 9 was used as a positive control. Treatment 9 was applied at the central spot on each side of the clipped flank areas.

Extraction: A glass ring (id=0.8 inch, height=0.8 inch) was firmly pressed to the designated spot so that extracting liquid would not leak out (Appendix 1). Two milliliters of designated extracting liquid for each treatment spot was added into the glass ring. The liquid in the glass ring was gently stirred with a glass rod for 2 minutes. Then, the extracting liquid was removed by aspiration using a pipette. The extracting process was repeated once. Afterwards, Panolgo Cream was applied on the treated area including treatment 1.

Below are the results.

An "X" indicates accelerated hair growth.

Table 1. Alcohol Treatments on Hair Growth of Beagles

Treatment	1	2	3	4	5	6	7	8	9R	9L
Dog ID	After 6 Treatments									
72BM		X				X			X	X
17AE										X
33AK							X		X	X
99AB					X	X	X	X	X	X
1XAK		X				X	X	X	X	X
3XBR		X	X		X	X		X	X	X
OXAL								X	X	X
30AC						X		X	X	X
8VET							X		X	X
04BA										X
2VAG						X	X	X	X	X
995AB										
37BS										
2XAV						X	X		X	X
3XAC						X			X	X
04AT							X			
7VCG										
Summary	0/17	3/17	1/17	0/17	2/17	8/17	7/17	6/17	11/17	13/17

It is clear that there was a real, significant effect on the rapidity of growth of hair on the canine involved in the test which is clearly due to the mixture of alcohols applied. These results are now reviewed.

Treatment 1 – the use of D-Squame sampling discs followed by Panolog cream (used in all test treatments) resulted in no effect.

Treatment 2 – use of ionized water plus Treatment 1 resulted in a small background effect.

Treatment 3- however the use of 5% methanol in water plus Treatment 1 resulted in even less activity than the background effect of Treatment 2.

Treatment 4 – the use of 5% isopropanol in water also gave the same effect as in Treatment 3.

Treatment 5 – the use of 90% ethanol in water provided the same effect, nil, as Treatments 3 and 4.

In short summary, the usage of certain quantities of certain alcohols alone in water – methanol, ethanol, and isopropanol – provided no greater acceleration of growing hair than water alone.

However, in Treatments 6 and 7, using ethanol and respectively methanol and isopropanol, significant increases in hair growth were observed. Treatment 8, done without D-Squame sampling but with a mixture of ethanol, methanol and isopropanol provided a significant effect. When D-Squame was added prior to contacting with the same mixture of ethanol (90%), methanol (5%) and isopropanol (5%) as used in Treatment 8, significantly greater hair growth was observed than in any of the other treatments.

The rejections are now commented upon, particularly in view of these results. Alopecia in dogs and cats is not a frivolous issue. As shown in the reference work, chapter 11 of Muller & Kirk's Small Animal Dermatology, 6th Edition, there are numerous types of alopecious including those acquired after clipping. These are serious issues for the pet owner, not frivolous. The acceleration of hair growth has been demonstratively shown in the above-reviewed data. Still further there are other compounds, quite a few now being actively sold for hair growth, so the overall utility is no longer seen as "unbelievable".

With respect to the 35 USC 112 rejection, the specification does provide a method as now claimed and also stated in the rejection for an increase in hair growth rate (accelerated). Our present data does show that it is the application of the alcohol which causes the growth of the hair, see the various treatments.

The rejection of claim 23 is rendered moot because of its cancellation.

The rejection under 35 USC 102 is not understood. There is no description anywhere that the group of alcohols claimed (ethanol, methanol, isopropanol, propanol) as the sole active agent can accelerate hair growth. This claim language excludes any other known hair growth agent from coverage. Huo teaches that a different, highly complex, multiple ring, water insoluble compound must be used. Our claims exclude this compound. This compound has no bearing whatsoever structurally to the combination of alcohols claimed in this application.

The Merck Veterinary manual adds nothing to the rejection under obviousness sincere there is a no disclosure which would make obvious the claimed combination of alcohols useful in the treatment of alopecia, particularly that brought about by clipping.

The use of Eggers also provides no motivation or direction to use the claimed composition for accelerating hair growth in a pet having alopecia. The reference is directed to treating viruses and has no disclosure motivating one of ordinary skill-in-the-art to utilize the claimed mixture of alcohols for accelerating hair growth in a pet having alopecia.

Whereupon applicants by their attorney respectfully request the allowance of the specification and pendant claims.

Respectfully submitted,

A handwritten signature in black ink that reads "Martin B. Barancik". The signature is written in a cursive, flowing style.

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